

REMARKS**Claim Amendment**

Claims 1 and 24 had been amended to recite that the conduit defined by the body extends throughout the body. Support for this amendment is found in FIG. 1(a), on page 6, lines 14-16 (the term “body” defined), page 6, lines 18-21 (conduit 34 is described as extending from the proximal portion of device 20 to the distal portion of device 20, and having inlet 38 and outlet 40), and on page 7, lines 3-5 (flowable material is injected through conduit 34 into the disk space).

This amendment introduces no new matter.

Claim Rejection Under 35 U.S.C. §102(b)

The Examiner rejected Claims 1-6 and 15 as being anticipated under 35 U.S.C. §102(b) by U.S. 6,375,655 (“Zdeblick *et al.*”). Referring to FIGs. 2 and 9 of Zdeblick *et al.*, the Examiner stated that Zdeblick *et al.* disclose a fusion device for use in the spine, comprising a body, having a proximal portion and a distal portion that defines conduit. The Examiner stated that the conduit is defined as an artificial channel or passage that is substantially parallel to the major axis. The Examiner further stated that Zdeblick *et al.* also disclose supporting means capable of supporting vertebrae in a distracted position while the vertebrae fuse. The Examiner stated that the “open inside” of the supporting means is considered a conduit in fluid communication with the conduit of the body.

Applicants amended independent Claims 1 and 24 to more particularly point out that the “conduit” extends throughout the body of the device as defined within the instant specification. Applicants submit that Claims 1 and 24 are novel in view of Zdeblick *et al.*

The present application describes the conduit defined by the body of the claimed device as extending from the proximal portion of device 20 to the distal portion of device 20, and having inlet 38 and outlet 40 (page 6, lines 18-21). With reference to FIG. 1(a), the present specification defines the “body” on page 6, lines 14-16: “the portion of device 20 that includes stopper 28, central section 30, clamp 32 and, preferably, connector 36 is referred to herein as the

“body” of the device.” FIG. 1(a) clearly illustrates that the conduit extends throughout the body of the device.

The relevant portion of the disclosure by Zdeblick *et al.* referenced by the Examiner is FIG. 9. The Examiner identifies the “body” of the device of Zdeblick *et al.* to be element 50, extending from proximal portion (end 52) to “the distal portion (opposite proximal end).” As stated at column 9, line 41 through column 10, line 6 and with reference of FIG. 9, referred to by the Examiner, interbody fusion device 10 of Zdeblick *et al.* is implanted by use of implant driver 50 that includes shaft 51 and sleeve 52. Tongs 54 are at one end of shaft 51. Shaft 51 defines hinge slot 62 which “is configured so that the tongs will have a naturally biased position spread sufficiently apart to accept the tapered interbody fusion device 10 therebetween.” As discussed at column 10, lines 1-8, “as the sleeve 52 is advanced toward tongs 54, the conical chamfer 67 rides against the conical taper 63 to close or compress the hinge slot 62.”

There is no disclosure in Zdeblick *et al.* of an intervertebral fusion device that includes a body having a proximal portion along a major axis of the body, and a distal portion and defining a conduit extending throughout the body, and further including supporting means at the distal portion of the body defining a conduit in fluid communication with the conduit defined by the body. More specifically, sleeve 52 of Zdeblick *et al.* does not include supporting means, and shaft 51 does not define a conduit that extends throughout the body. Element 62 does not have an inlet and an outlet, like the conduit of the device of the present invention; element 62 fails to extend throughout the body of the device of Zdeblick *et al.*. Therefore, Zdeblick *et al.* does not teach each and every element of the device defined in Claims 1 and 24 of the present application.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claim Rejection Under 35 U.S.C. §103(a)

The Examiner rejected Claims 11-13 and 24 as being obvious under 35 U.S.C. §103(a) over Zdeblick *et al.* in view of U.S. Pub. No. 2003/0028251 (“Mathews”). The Examiner stated that Zdeblick *et al.* disclose the present invention except for a supporting means that is a balloon and flowable materials capable of facilitating bone growth. The Examiner stated that Mathews discloses the elements of the present invention not taught by Zdeblick *et al.*

As stated in M.P.E.P. §2143:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Applicants note that the combination of Zdeblick *et al.* and Mathews fails to teach or suggest all the elements of the claimed invention. Specifically, as presented above, Zdeblick *et al.* fails to teach a conduit extending throughout the body. Applicants further note that Mathews' balloon is used merely as a distracting means (see paragraphs [0050]-[0053], and [0056]).

Zdeblick *et al.* do not disclose or suggest that supporting means can include a balloon. Mathews does not remedy the deficiency of Zdeblick *et al.* In particular, there is no disclosure in Mathews that the balloon employed to distract vertebrae has a height distinct from a width taken along a cross-section of a portion of the body or supporting means of the intervertebral fusion device, whereby the portion of the body or supporting means can distract vertebrae, between which the portion of the body or supporting means has been placed, by rotation of the body or the supporting means about a major axis, as in Applicants' claimed intervertebral fusion device. Further, there is no disclosure or suggestion in Zdeblick *et al.* to modify hinge slot 62 to extend through shaft 51, as would be necessary to fill a balloon at its distal portion.

Motivation to combine the teachings of Zdeblick *et al.* and Mathews to obtain Applicants' claimed intervertebral fusion device can only found in Applicants' specification and claims. Therefore, Applicants' claimed intervertebral fusion device meets the requirements of 35 U.S.C. §103(a).

Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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Dated: *10/5/06*